

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

510961

PCT/JP2003/005593



Applicant's or agent's file reference 142413-999	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/005593	International filing date (day/month/year) 01 May 2003 (01.05.2003)	Priority date (day/month/year) 01 May 2002 (01.05.2002)
International Patent Classification (IPC) or national classification and IPC C07D 215/22, 417/12, A61K 31/47, 31/4709, 31/5377, A61P 19/02, 19/10, 29/00, 35/00, 35/04, 43/00		
Applicant KIRIN BEER KABUSHIKI KAISHA		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>7</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 26 September 2003 (26.09.2003)	Date of completion of this report 30 March 2004 (30.03.2004)
Name and mailing address of the IPBA/JP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP2003/005593

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 91, 92

because:

- ☒ the said international application, or the said claims Nos. 91, 92
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 91, 92

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

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PCT/JP93/05593

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

Claims 91 and 92 pertain to methods for treatment of the human body by surgery or therapy, and thus relate to subject matter which does not require international preliminary examination by this International Preliminary Examining Authority.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7. 13-15, 17-85	YES
	Claims	1-6, 8-12, 16, 86-90	NO
Inventive step (IS)	Claims		YES
	Claims	1-90	NO
Industrial applicability (IA)	Claims	1-90	YES
	Claims		NO

2. Citations and explanations

Documents

1. EP 860433 A1 (Kirin Beer KK), 26 August 1998
2. EP 1153920 A1 (Kirin Beer KK), 14 November 2001
3. WO 02/32872 A1 (Eisai Co., Ltd.), 25 April 2002

Explanations

Claims 1-6, 8-12, 16 and 86-90

The inventions set forth in claims 1-6, 8-12, 16 and 86-90 are not novel and do not involve an inventive step in the light of document 1, cited in the international search report.

Document 1 discloses a compound represented by formula (I) presented in claim 1 in the present application in which X is CH, Z is O, R¹, R⁴ and R⁵-R¹¹ are hydrogen atoms, R² and R³ are methoxy, R¹² is methyl and R¹³ is naphthyl (compound no. 231).

The inventions set forth in claims 1-6, 8-12, 16 and 86-90 also do not involve an inventive step in the light of documents 1-3, cited in the international search report.

Documents 1-3 disclose sets of compounds which include compounds represented by formula (I) presented in claim 1 in the present application and are efficacious for the treatment of tumours and tumour metastasis and disorders such as rheumatoid arthritis. Therefore, given the disclosures in these documents in the examples, etc., a person skilled in the art could easily conceive of attempting to actually prepare compounds included in the aforementioned sets of compounds and confirm their pharmacological effects.

Claims 7, 13-15 and 17-85

The inventions set forth in claims 7, 13-15 and 17-85 are not disclosed in any of the documents cited in the international search report, and are novel; however, they do not involve an inventive step in the light of documents 1-3, cited in the international search report.

Documents 1-3 disclose sets of compounds which include compounds described in claims 7, 13-15 and 17-85 in the present application and are efficacious for the treatment of tumours and tumour metastasis and disorders such as rheumatoid arthritis. Therefore, given the disclosures in these documents in the examples, etc., a person skilled in the art could easily conceive of attempting to actually prepare compounds included in the aforementioned sets of compounds and confirm their pharmacological effects.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/033472 A1 [EX]	24 April 2003 (24.04.2003)	17 October 2002 (17.10.2002)	17 October 2001 (17.10.2001)

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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